



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Date: 17-JUL-2008

SUBJECT: **Pyrimethanil.** Application for Amended Section 3 Registration of Xedathane™ A for Postharvest Use on Pome Fruits by Thermafog Application.

PC Code: 288201

DP Nos.: 347247 and 347248

Decision No.: 382439

Registration No.: 64864-xx

Petition No.: 7F7250

Regulatory Action: Amended Section 3

Risk Assessment Type: NA

Case No.: NA

TXR No.: NA

CAS No.: 53112-28-0

MRID No.: See MRID Summary Table

40 CFR: 180.518

FROM: George F. Kramer, Ph.D., Senior Chemist
Registration Action Branch (RAB1)
Health Effects Division (HED) (7509P)

THROUGH: Dana M. Vogel, Branch Chief
RAB1/HED (7509P)

TO: Tamue Gibson/Mary Waller, Risk Manager 21
Registration Division (RD; 7505P)

MRID Summary Table		
MRID No.	Study Type	Comments
47201502	860.1500 Pome Fruit	New DER;
47226701		47201502.der.doc (includes MRID 47226701)
47203201	860.1500 Pome Fruit	New DER;
47271201		47203201.der.doc (includes MRID 47271201)

This document was originally prepared under contract by Dynamac Corporation (2275 Research Blvd, Suite 300; Rockville, MD 20850; submitted 04/07/2008). The document has been reviewed by HED and revised to reflect current Office of Pesticide Programs (OPP) policies.

Executive Summary

Pace International LLC has submitted a Section 3 registration application for Xedathane™ A (EPA File Symbol No. 64864-xx), an aqueous suspension-concentrate (SC) formulation containing 16% pyrimethanil. Xedathane™ A is proposed for postharvest use on pome fruits as an aerosol via thermal fogging to control blue and gray mold at an application rate of 9.6 g ai/metric ton of fruit (or 0.3 oz ai/U.S. ton). The proposal to register Xedathane™ A will supplement the available pyrimethanil end-use products (EPs) currently registered for preharvest and postharvest uses on pome fruits.

Pyrimethanil tolerances are currently established in 40 CFR §180.518 and are expressed in terms of: (i) parent only for plant commodities; (ii) parent + Metabolite AEC614276 (4-[4,6-dimethyl-2-pyrimidinyl]amino]phenol) for ruminant tissues; and (iii) parent + Metabolite AEC614277 (4,6-dimethyl-2-(phenylamino)-5-pyrimidinol) for milk.

As a result of the proposed postharvest uses of Xedathane™ A on pome fruits, Pace International LLC, proposes to amend 40 CFR §180.518 (a)(1) to increase the established tolerances for the residues of the fungicide 4,6-dimethyl-*N*-phenyl-2-pyrimidinamine, expressed as pyrimethanil, in/on:

Pome Fruits (Crop Group 11)from 3 ppm to 14.0 ppm
Pome Fruit – Wet Pomacefrom 12 ppm to 56.0 ppm

The petitioner also proposes to amend 40 CFR §180.518 (a)(2) to increase the tolerance for the combined residues of the fungicide 4,6-dimethyl-*N*-phenyl-2-pyrimidinamine, expressed as pyrimethanil, and its metabolite 4-[4,6-dimethyl-2-pyrimidinyl) amino]phenol in:

Kidney of cattle, goat, horse, and sheepfrom 0.30 ppm to 0.6 ppm

Finally, the petitioner proposes to amend 40 CFR §180.518 (a)(3) to increase the tolerance for the combined residues of the fungicide 4,6-dimethyl-*N*-phenyl-2-pyrimidinamine, expressed as pyrimethanil, and its metabolite 4,6-dimethyl-2-(phenylamino)-5-pyrimidinol in:

Milk.....from 0.03 ppm to 0.06 ppm

The qualitative nature of the pyrimethanil residue in plant commodities is adequately understood based on acceptable metabolism studies in lettuce, grapes, and tomatoes. The HED Metabolism Assessment Review Committee (MARC) has determined that for risk assessment and tolerance expression that the parent is the only residue of concern. Future new uses on root crops whose tops are significant food/feed items will require the analysis of metabolite AEC614278.

The qualitative nature of the residue in ruminant is adequately understood. The HED MARC concluded that for risk assessment and the tolerance expression, parent, AEC614276 (tissues only), and AEC614277 (milk only) are the residues of concern. A poultry metabolism study has not been submitted and is not necessary for the proposed use on pome fruits.

A high-performance liquid chromatography (HPLC) residue analytical method entitled, “Analytical Method for the Determination of Residues of ZK 100309 in Vines, Strawberries, and Apples by HPLC” was submitted in conjunction with an earlier pyrimethanil petition, PP#4E4384, for the establishment of a tolerance on imported wine grapes. The method has been subjected to a successful independent laboratory validation (ILV) and was subsequently forwarded to Analytical Chemistry Branch (ACB)/Biological and Economics Analysis Division (BEAD) for a successful petition method validation (PMV).

The data collection method used to generate residue data in conjunction with magnitude of the residue studies associated with this petition is a gas chromatography/mass spectroscopy (GC/MS) method. The limit of quantitation (LOQ) ranged 0.03-0.05 ppm; the reported limit of

detection (LOD), determined by the lowest level of the calibration line, was 0.025 ppm. The adequacy of the GC/MS method for data collection was verified by fortifying control samples of apples with pyrimethanil at tolerance-setting levels. Method recoveries were within the acceptable range of 70-120% for all fortified samples.

The available livestock analytical method targets pyrimethanil and AEC614276 in tissues and additionally AEC614277 in milk. Following methylation, samples are analyzed by GC/MS/MS. The LOQ for each analyte has been set at 0.01 ppm in milk and 0.05 ppm in livestock tissues. The ILV of this method was deemed adequate, and the method was subsequently forwarded to ACB/BEAD for a PMV (DP# 288255, 3/10/2003, G. Kramer). ACB/BEAD concluded that the analytical method only marginally meets the applicable guideline requirements to enforce livestock tolerances and recommended that further laboratory validation of this method was necessary before permanent tolerances were granted (DP# 288256, 7/7/2004, E. Kolbe). Since GC ion-trap MS/MS has not panned out as a robust quantitative instrument, ACB/BEAD is now recommending that the petitioner revise the method to use liquid chromatography with tandem mass spectrometry (LC-MS/MS) for pyrimethanil and its metabolites (E-mail from C. Stafford of ACB/BEAD, 4/23/08). If Bayer can provide adequate recovery data using an LC-MS/MS method in livestock commodities, then an ILV will not be required.

Adequate postharvest data, reflecting the proposed thermal fogging of fruits according to label directions, were submitted for apples and pears, the representative crops of fruit, pome, group 11. These data indicate that following one postharvest treatment via thermal fogging of pome fruits using an SC formulation at 0.32-0.38 oz ai/ton (1.0-1.3x the proposed rate), maximum residues of pyrimethanil were 4.1 ppm in/on pears and 9.47 ppm in/on apples. The available data suggest that the proposed crop group tolerance of 14 ppm for pome fruits will not be exceeded when maximum residues from all routes of pyrimethanil exposure to pome fruits are considered (preharvest + postharvest by line spray aqueous and wax + postharvest by thermal fogging). Maximum residues following preharvest treatment at 1.59-1.62 lb ai/A (1.0x) and PHIs of 71-73 days were 0.16 ppm for apples and <0.05 ppm for pears (DP#s 284001 & 284870, 01/12/2004, J. Morales and G. Kramer). Maximum residues following postharvest treatment by line spray aqueous and wax at 1x were 2.84 ppm

An acceptable apple processing study with pyrimethanil is available. The results indicate that residues of pyrimethanil reduced in apple juice (processing factor of 0.35x) but increased in wet pomace (processing factor of 4.1x). Based on the multiplication of maximum residues observed from the postharvest study (9.47 ppm) by the processing factor for wet pomace (4.1x), the maximum expected residue of pyrimethanil in apple wet pomace is 38.8 ppm. The proposed tolerance value of 56 ppm for apple wet pomace may be lowered to 40 ppm in order to achieve compatibility with the Codex maximum residue limit (MRL) for apple dry pomace; a revised Section F is required for this purpose. A tolerance for residues in apple juice is not needed.

An acceptable ruminant feeding study is available. Following adjustment of residues for storage stability and calculations of transfer coefficient factors, the recommended tolerances are 2.5 ppm for the kidney of cattle, goat, horse, and sheep and 0.05 ppm for milk. Only the tolerances for milk and kidney will be affected as all other ruminant commodity tolerances were set at the LOQ of the enforcement method (no residues of concern were identified in these tissues in the ruminant metabolism and feeding studies).

Analytical standards for pyrimethanil, with an expiration date 09/01/2008, are currently available in the EPA National Pesticide Standards Repository. However, standards for the regulated metabolites (AEC614276 and AEC614277) are not available and should be submitted.

Pome fruits are typically not rotated. Therefore, residue data pertaining to confined and field accumulation in rotational crops are not germane to this tolerance petition.

Regulatory Recommendations and Residue Chemistry Deficiencies

Pending submission of a revised Section B (see requirements under Directions for Use), the submission of analytical standards for the regulated metabolites (see requirements under Submittal of Analytical Reference Standards), and a revised Section F (see requirements under Proposed Tolerances), there are no residue chemistry issues that would preclude granting a conditional registration for the requested uses of Xedathane™ A on pome fruits and the following permanent tolerances:

Fruits, pome, group 11 ¹	14 ppm
Apple, wet pomace ¹	40 ppm
Cattle, kidney ²	2.5 ppm
Goat, kidney ²	2.5 ppm
Horse, kidney ²	2.5 ppm
Sheep, kidney ²	2.5 ppm
Milk ³	0.05 ppm

¹ Expressed in term of parent only.

² Expressed in terms of parent + Metabolite AEC614276.

³ Expressed in terms of parent + Metabolite AEC614277.

The registration may be made unconditional upon submission of revised residue analytical methods for livestock commodities (see requirements under Residue Analytical Methods).

Note to RD: The tolerance expression listed in 40 CFR 180.518 (a)(2) should be revised to correct the metabolite name. The expression in 180.518 (a)(2) should be revised to: “the combined residues of the fungicide pyrimethanil 4,6-dimethyl-*N*-phenyl-2-pyrimidinamine and its metabolite 4-[4,6-dimethyl-2-(pyrimidinyl) amino]phenol.”

860.1200 Directions for Use

Label revision is required to clearly specify that Xedathane™ A may only be applied once for postharvest use by electrofog machine on pome fruits and to prohibit application to fruit that has been previously treated with pyrimethanil via drench or dip/wash application.

860.1340 Residue Analytical Methods

ACB/BEAD does not currently have the GC/MS/MS ion trap instrument necessary to validate the proposed enforcement method for livestock. Since GC ion-trap MS/MS has not panned out as a robust quantitative instrument, ACB/BEAD is now recommending that the petitioner revise the method to use LC-MS/MS for pyrimethanil and its metabolites (E-mail from C. Stafford of ACB/BEAD, 4/23/08). If Bayer can provide adequate recovery data using an LC-MS/MS method in livestock commodities, then an ILV will not be required.

860.1650 Submittal of Analytical Reference Standards

Analytical reference standards of the regulated metabolites (AEC614276 and AEC614277) should be supplied and supplies replenished as requested by the Repository. The reference standards should be sent to the Analytical Chemistry Lab, which is located at Fort Meade, to the attention of either Theresa Cole or William Chism at the following address:

USEPA

National Pesticide Standards Repository/Analytical Chemistry Branch/OPP

701 Mapes Road

Fort George G. Meade, MD 20755-5350

(Note that the mail will be returned if the extended zip code is not used.)

860.1550 Proposed Tolerances

A summary of the recommended tolerances along with recommendations for commodity definitions are presented in Table 11. The petitioner is required to submit a revised Section F to reflect the recommendations in Table 11.

A human-health risk assessment will be prepared as a separate document.

Background

Pyrimethanil is an anilinopyrimidine fungicide that inhibits the secretion of fungal enzymes which are required during the infection process. Pyrimethanil blocks the ability of the fungus to degrade and digest the plant tissues, thus stopping penetration and development of the disease. The precise mechanism of inhibition of enzyme secretion has not been fully established. Protein synthesis is not inhibited, and evidence suggests that extracellular enzymes accumulate inside the fungus, their release being blocked in the presence of the fungicide. Pyrimethanil penetrates rapidly into the plant tissues, where it stops the development of the disease, providing a significant curative action. *In vitro*, germ tube extension and mycelial growth are inhibited.

Pyrimethanil does not exhibit cross-resistance to sterol-inhibitors, dicarboximides, benzimidazoles, quinone outside inhibitors, or phenylamides, but may exhibit cross-resistance in certain plant pathogenic fungi including anilinopyridine (AP) compounds such as cyprodinil and mepanipyrim. The nomenclature of pyrimethanil is summarized in Table 1. The physicochemical properties of pyrimethanil are summarized in Table 2.

Table 1. Test Compound Nomenclature.

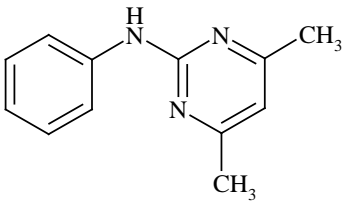
Compound	
Common name	Pyrimethanil
Company experimental names	Janssen: R215559; PH0666 Aventis: SN 100309; ZK 100309; AE B100309
IUPAC name	2-Anilino-4,6-dimethylpyrimidine
CAS name	4,6-Dimethyl-N-phenyl-2-pyrimidinamine
CAS registry number	53112-28-0
End-use product (EP)	Xedathane A (EPA File Symbol No. 64864-xx), an aqueous SC formulation containing 16% pyrimethanil

Table 2. Physicochemical Properties of Pyrimethanil.

Parameter	Value	Reference
Melting point	~95 °C	43301601
pH	Data unavailable	
Density	Bulk density = 650-700 Kg/m ³	43301601
Water solubility (25 °C)	0.121 g/L (pH 6.1)	44908503
Solvent solubility (g/L at 20 °C)	Dichloromethane: 1000.2 Ethyl acetate: 616.9 Acetone: 388.8 n-Hexane: 23.7	44908503
Vapor pressure at 25 °C	2.2 x 10 ⁻³ Pa	44908503
Dissociation constant (pK _a)	pK _a = 3.52 ± 0.02	43301601
Octanol/water partition coefficient Log(K _{ow})	2.48	http://www.hb-p.com/pyrimethanil.htm
UV/visible absorption spectrum	Data unavailable	

860.1200 Directions for Use

Pace International LLC has submitted a proposed label for a 16% liquid formulation, Xedathane™ A (EPA File Symbol No. 64864-xx) proposed for postharvest use on pome fruits. The product is applied undiluted through a thermal electrofogger.

HED notes that the proposed label for Xedathane™ A states on the front page of the label that the product is a special liquid form of pyrimethanil intended for use with a Xeda Brand Thermal Electrofogger to form a fine fog. Under Section A of the petition, the end product composition is identified as an aqueous SC fungicide formulation containing 16% pyrimethanil.

The proposed directions for use with Xedathane™ A (EPA File Symbol No. 64864-xx) on pome fruits are presented in Table 3.

The paragraphs below list the registered pyrimethanil EPs and briefly describe the use patterns which are currently registered for use on pome fruits.

Scala™ SC Fungicide (EPA Reg. No. 264-788) is a SC formulation registered to Bayer CropScience for preharvest uses on apples, pears, crabapple, loquat, mayhaw, and quince. The initial HED review of tolerance petitions (PP#s 2F06439 and 2F06480. J. Morales and G. Kramer, DP#s 284001 & 284870, 01/12/2004) for uses on various crops including pome fruits reported that Scala™ contains 37.4% pyrimethanil (3.34 lb ai/gal); however, an updated specimen label Scala™ specifies that it now contains 54.6% pyrimethanil (5.0 lb ai/gal). Scala™ is registered for multiple foliar spray treatments of pome fruits for the control of scab (*Venturia* spp.) using ground or aerial equipment at a maximum rate of 0.39 lb ai/A/application with a 7-day retreatment interval. The maximum seasonal rate is 1.6 lb ai/A, and the established preharvest interval (PHI) is 72 days.

Penbotec™ 400 SC Fungicide (PH066 SC) (EPA Reg. No. 43813-32) is a SC formulation registered to Janssen Pharmaceutica for postharvest uses on pome fruits to control gray mold and blue mold. Penbotec™ contains 37.14% pyrimethanil (3.27 lb ai/gal). The registered postharvest application methods (and maximum rates in parentheses) include dip/wash tanks (1,000 ppm), drenchers (1,000 ppm), and line spray (aqueous and wax, 2,000 ppm).

Table 3. Summary of Directions for Use of Pyrimethanil.						
Applic. Timing, Type, and Equip.	Formulation [EPA Reg. No.]	Applic. Rate	Max. No. Applic. per Season	Max. Seasonal Applic. Rate	PHI (days)	Use Directions and Limitations
Pome Fruits						
Postharvest Electrofog Machine	SC ¹ [64864-xx]	9.6 g ai/metric ton of fruit (or 0.3 oz ai/US ton)	Not applicable (NA)	NA	NA	Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. Do not apply this product on fruit that has been previously treated with pyrimethanil via drench application.
	<u>Recommendations</u> Treat only dry fruit as received from the field. Apply to fruit as close to harvest as possible and no more than 15 days after harvesting, prior to placing in storage. Before treatment, fruit in bins at the top of each stack should be protected with plastic liners, cardboard, or Kraft paper sheets. Fruit directly in front of the fogging equipment should also be protected with liners or sheets from top to bottom. When treating rooms that are not completely filled, calculate the dosage of Xedathane™ A by adding a tonnage value of 20% of the empty volume to the real tonnage of the fruit. <u>Electrofogger Operation</u> Place the Electrofog machine horizontally outside the treatment room at a height of about 3 feet from the floor. Cover the door or window to the treatment room with a plastic sheet and insert the fogging pipe through a hole in the plastic. Place a bucket under the nozzle to catch any drops. Seal the opening around the nozzle so no fog can escape during treatment. Set the Electrofog machine resistance temperature between 500° to 600°C. Insert input pipe into product container and start pump. Stop pump when product reaches the pump body. Start fan and resistance, and start pump again when fog exit temperature reaches 180° C. Adjust pump as necessary during operation to maintain 180°C. <u>Application Procedures</u> Avoid breathing the fog. Turn off cooling systems and humidifiers 12 hours prior to and during treatment. Turn off circulation fans immediately prior to and during treatment. Allow fog to stay overnight or until the fog has totally disappeared (about 5 hours posttreatment) before restarting fans and cooling systems. Do not rinse apples after treatment. <u>Re-Entry</u> Entry into the treatment area by any person other than properly trained and equipped handlers is prohibited from the start of the application until the treated area is ventilated as follows: 8 hours with no ventilation followed by 1 hour of mechanical ventilation; or 24 hours with no ventilation. In case it is necessary to enter during treatment or before ventilation requirements have been met, handlers must wear chemical-resistant headgear and a self contained breathing apparatus.					

¹ SC = suspension concentrate formulation; product is applied undiluted.

Conclusions. The submitted label for Xedathane™ A is adequate to allow evaluation of the residue data relative to the proposed postharvest use by electrofog machine. However, HED recommends label revisions to clearly specify that Xedathane™ A may only be applied once for postharvest use by electrofog machine on pome fruits and to prohibit application to fruit that has been previously treated with pyrimethanil via drench or dip/wash application (the tolerance is based on preharvest + postharvest by line spray aqueous and wax + postharvest by thermal fogging).

860.1300 Nature of the Residue – Plants & Livestock

DP#s 284001 & 284870, 01/12/2004, J. Morales and G. Kramer (PP#s 2F06439 and 2F06480)

The qualitative nature of the pyrimethanil residue in plant commodities is adequately understood based on acceptable metabolism studies in lettuce, grapes, and tomatoes. The HED Metabolism Assessment Review Committee (MARC) has determined that for risk assessment and tolerance expression, parent only is the residue of concern. Future new uses on root crops whose tops are significant food/feed items will require the analysis of metabolite AEC614278.

A ruminant metabolism study indicated that the major residue is AEC614276 (see Figure 1 for chemical structure), which accounted for 46% of TRR in kidney and 64% TRR in milk. Metabolite AEC614277 is a minor metabolite and accounted for 5% of TRR in kidney. However, in the feeding study, AEC614277 was found only in milk and AEC614276 was quantifiable only in some tissues. The method was originally designed only for parent + AEC614276, but the milk samples contained an unidentified peak (determined to be AEC614277). The method was then validated for residues of AEC614277 in milk only. The petitioner explained the discrepancy between the feeding and metabolism studies as an error in identification of the major milk metabolite in the metabolism study. The identification was based only on thin-layer chromatography (TLC) as low levels of radioactivity precluded use of MS. The metabolites AEC614276 & AEC614277 were not well resolved, so that AEC614277 was probably the major metabolite in the metabolism study. Based on the results of the metabolism study and the feeding study, and the fact that both AEC614276 and AEC614277 are likely to share the same toxicity as the parent (from structure similarity), MARC concluded that for risk assessment and the tolerance expression, parent, AEC614276 (tissues only), and AEC614277 (milk only) are the residues of concern. Analytical methods are available to detect these metabolites.

A poultry metabolism study is not required as there are no poultry feedstuffs associated with the proposed use on pome fruits. Table 4 is a summary of the HED MARC decisions concerning the residues of concern in plants, ruminants, and milk for tolerance expression and risk assessment purposes.

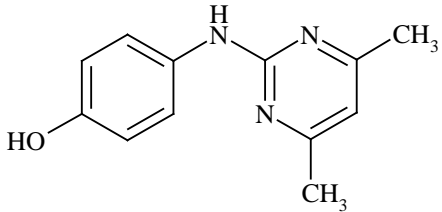
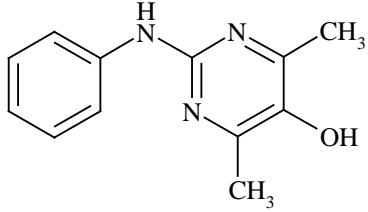
Figure 1. Structures of Major Pyrimethanil Metabolites.		
Common name/code ID No.	Chemical name	Chemical structure
AEC614276	4-[4,6-dimethyl-2-(pyrimidinyl)amino]phenol	
AEC614277	4,6-dimethyl-2-(phenylamino)-5-pyrimidinol	

Figure 1. Structures of Major Pyrimethanil Metabolites.

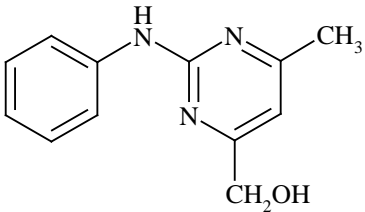
AEC614278	6-methyl-2-(phenylamino)-4-pyrimidinemethanol	
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Table 4. Residues of Concern in Plants and Ruminants.

Matrix	For Risk Assessment	For Tolerance Expression
Plants	Parent Only	Parent Only
Ruminant	Parent + AEC614276	Parent + AEC614276
Milk	Parent + AEC614277	Parent + AEC614277

860.1340 Residue Analytical Methods

DP# 284866, 11/15/2004, D. Vogel, *et al.*

Enforcement methods

A residue analytical method entitled “Analytical Method for the Determination of Residues of ZK 100309 in Vines, Strawberries, and Apples by HPLC” was submitted in conjunction with an earlier pyrimethanil petition, PP#4E4384, for the establishment of a tolerance on imported wine grapes. The method has been subjected to a successful PMV by ACB/BEAD (DP# 288256, 7/7/2004, E. Kolbe).

The livestock analytical method targets pyrimethanil and AEC614276 in tissues and additionally AEC614277 in milk. Following methylation, samples are analyzed by GC/MS/MS. The LOQ for each analyte has been set at 0.01 ppm in milk and 0.05 ppm in livestock tissues. The ILV of this method was deemed adequate, and the method was subsequently forwarded to ACB/BEAD for a PMV (DP# 288255, 3/10/2003, G. Kramer). ACB/BEAD concluded that the analytical method only marginally meets the applicable guideline requirements to enforce livestock tolerances and recommended that further laboratory validation of this method was necessary before permanent tolerances were granted (DP# 288256, 7/7/2004, E. Kolbe). Since GC ion-trap MS/MS has not panned out as a robust quantitative instrument, ACB/BEAD is now recommending that the petitioner revise the method to use LC-MS/MS for pyrimethanil and its metabolites (E-mail from C. Stafford of ACB/BEAD, 4/23/08). If Bayer can provide adequate recovery data using an LC-MS/MS method in livestock commodities, then an ILV will not be required.

Data-collection method(s)

The data-collection method used to generate residue data in conjunction with magnitude of the residue studies associated with this petition is a GC/MS method entitled “Fruit – Determination of R215559 and R023979 by Gas Chromatography-Mass Spectrometry (GC/MS).” Briefly, samples of fruit, with NaCl added, were extracted with ethyl acetate:isohexane (50:50, v:v) containing a pentachlorobenzene internal standard. The supernatant was allowed to separate.

Anhydrous sodium sulfate was added to dry the extract and the dried extract submitted for GC/MS determination of residues of pyrimethanil. The LOQ, defined as the lowest limit of method validation for which adequate recovery was obtained, ranged 0.03-0.05 ppm; the reported LOD, determined by the lowest level of the calibration line, was 0.025 ppm. The adequacy of the GC/MS method for data collection was verified by fortifying control samples of apples with pyrimethanil at tolerance-setting levels. Method recoveries were within the acceptable range of 70-120% for all fortified samples.

860.1360 Multiresidue Methods

DP#s 284001 & 284870, 01/12/2004, J. Morales and G. Kramer (PP#s 2F06439 and 2F06480)

Pyrimethanil was tested through Protocols C, D, and E of the standard Food and Drug Administration (FDA) Multiresidue Protocols. Pyrimethanil was found to be nondetectable by the electron-capture (EC) detector. The use of a nitrogen-specific detector is recommended. Recovery was complete (>100%) using the Luke procedure for grapes (non-fatty food) fortified at 0.05 and 5.0 ppm. No recovery was obtained from cottonseed oil (fatty food) fortified at 0.05 ppm. For cottonseed oil fortified at 0.5 ppm, average recoveries of 28% (range 16-40%) and 78% (range 75-82%) were obtained when using the ether and the methylene chloride system, respectively. Pyrimethanil eluted from the standardized Florisil column. Recovery ranged from 86 to 98% using two different systems.

860.1380 Storage Stability

DP#s 284001 & 284870, 01/12/2004, J. Morales and G. Kramer (PP#s 2F06439 and 2F06480)

Samples of apples that were collected from the postharvest residue studies associated with this petition were stored frozen prior to residue analysis for durations of <30 days to 233 days. No supporting storage stability data were included in the review package. However, it has been previously reported that residues of pyrimethanil are reasonably stable under frozen storage conditions in/on apples for up to 676 days.

860.1480 Meat, Milk, Poultry, and Eggs

Tolerances are currently established in 40 CFR §180.518 (a)(2) for the combined residues of pyrimethanil and its metabolite 4-[4,6-(dimethyl-2-pyrimidinyl) amino]phenol in:

Fat of cattle, goat, horse, and sheep	0.01 ppm
Kidney of cattle, goat, horse, and sheep	0.30 ppm
Meat of cattle, goat, horse, and sheep	0.01 ppm
Meat byproducts (except kidney) of cattle, goat, horse, and sheep	0.01 ppm

The petitioner proposes to amend 40 CFR §180.518 (a)(2) to increase the tolerance for kidney from 0.30 ppm to 0.6 ppm as a result of the proposed postharvest use of Xedathane™ A on pome fruits. No adjustment of tolerances is being requested for fat, meat, and meat byproducts (except kidney).

A tolerance for the combined residues of pyrimethanil and its metabolite 4,6-dimethyl-2-(phenylamino)-5-pyrimidinol is currently listed in 40 CFR §180.518 (a)(3) for:

Milk..... 0.03 ppm

The petitioner now proposes to amend 40 CFR §180.518 (a)(3) to increase the tolerance for milk from 0.03 ppm to 0.06 ppm.

Livestock Dietary Burdens

The only livestock feedstuff associated with the proposed use discussed in this petition is wet apple pomace. For the estimation of dietary burdens of pyrimethanil to beef and dairy cattle, only wet apple pomace was used in the calculation (see Table 5) since it is very unlikely that more than one minor feed item (i.e., apple pomace, dried citrus pulp, and almond hulls) will be used at this time. There are no poultry and swine feedstuffs associated with the proposed uses.

Table 5. Livestock Dietary Burdens for Pyrimethanil.					
Feedstuff	Feedstuff Type ¹	% Dry Matter ²	% Diet ²	HED-Recommended/ Established Tolerance (ppm)	Dietary Contribution (ppm) ³
Beef Cattle					
Dried citrus pulp	R	91	10	10	1.1
TOTAL BURDEN	--		10 ⁴		
Dairy Cattle					
Apple pomace, wet	CC	40	10	40	10
TOTAL BURDEN	--	--	10 ⁴		

¹ R = Roughage, CC = Carbohydrate concentrate.

² Table 1 Feedstuffs (April, 2008).

³ Contribution = (tolerance /% DM x % in diet) for beef and dairy cattle.

⁴ The remainder of the diet will be composed of feedstuffs (i.e., roughage and protein concentrate sources) derived from crops that do not have registered pyrimethanil uses/tolerances.

Dairy Cattle Feeding Study

DP#s 332808 & 333354, 07/16/2007, G. Kramer (PP#s 2F06439 and 2F06480)

DP#s 284001 & 284870, 01/12/2004, J. Morales and G. Kramer (PP#s 2F06439 and 2F06480)

A dairy cattle feeding study (MRID 45657122) with pyrimethanil was initially reviewed in a memorandum dated 01/12/2004 (DP#s 284001 & 284870, J. Morales and G. Kramer) and was subsequently re-evaluated on 07/16/2007 (DP#s 332808 and 333354, G. Kramer) following receipt of storage stability data for milk and ruminant tissues which showed significant degradation of residues during storage. The dairy cattle feeding study is briefly summarized below.

Pyrimethanil was administered by gelatin capsule to 14 Holstein lactating cattle for 28 days. Dosing was made at 1.0, 3.0, 10, and 50 mg/kg feed. Milk samples were collected twice daily and tissue samples were collected within 5 hours of administration of the final dose. In milk, pyrimethanil residues consisted almost entirely of metabolite AEC614277. There were no

detectable (<0.0033 ppm) residues of the parent at the 50 ppm dose level. Residues of AEC614276 were either not detected or below the LOQ (0.01 ppm) at the 50 ppm dose level. Quantifiable residues of AEC614277 were found in milk samples from the 10 ppm and 50 ppm dose levels. Residues at the 3.0 ppm dose level were <LOQ. Residues appeared to plateau by day 20 and were generally linear with dose level. The results of the feeding study, adjusted to incorporate the storage stability data and reproduced from the 07/16/2007 memorandum (DP#s 332808 and 333354, G. Kramer), are presented in Table 6.

Only the tolerances for milk and kidney will be affected as all other ruminant commodity tolerances were set at the LOQ of the enforcement method (no residues of concern were identified in these tissues in the ruminant metabolism and feeding studies).

Table 6. Summary of Residue Data from Ruminant Feeding Study with Pyrimethanil.			
Matrix	Feeding Level (ppm)	Analyte	Maximum Residue Levels (ppm)
Milk- Day 27	3	AEC614277	ND
	10	AEC614277	0.044 ¹
	50	Pyrimethanil	ND
		AEC614276	<LOQ
		AEC614277	0.230 ¹
Kidney	1	Pyrimethanil	<LOQ
		AEC614276	<LOQ
	3	Pyrimethanil	ND
		AEC614276	1.04 ²
	10	Pyrimethanil	ND
		AEC614276	1.69 ²
	50	Pyrimethanil	ND
		AEC614276	11.4 ²

¹ Corrected for losses during of storage (6 months) based on the estimated half-life value of 130 days.

² Corrected for losses during storage (6 months) based on the estimated half-life value of 48.8 days.

Expected secondary residues in kidney and milk

To assess the adequacy of the proposed new tolerances for kidney and milk, the secondary residues were estimated using transfer coefficient factors based on maximum residues of parent + metabolite of concern observed at all dose levels where quantifiable residues were observed (average value). The transfer coefficients (calculated as residue level to feed level ratios) are presented in Table 7. The transfer coefficient for each matrix was then used to calculate the expected secondary residues by multiplying the transfer coefficient by the calculated dietary burden. The expected residues of pyrimethanil and the recommended tolerances based on expected residues are presented in Table 8.

Table 7. Transfer coefficients (calculated as residue level to feed level ratios)¹.	
Tissue	Ratio
Kidney	0.248
Milk	0.0045

¹ Based on maximum residues of parent + metabolite of concern observed all dose levels where quantifiable residues were observed (average value).

Table 8. Expected Secondary Residues of Pyrimethanil in Kidney and Milk.			
Matrix	Dietary Burden	Secondary Residues ¹	Recommended Tolerance

	(ppm)	(ppm)	(ppm)
Kidney	10 (Dairy Cattle)	$10 \times 0.248 = 2.48$	2.5
Milk	10 (Dairy Cattle)	$10 \times 0.0045 = 0.045$	0.05

¹ Calculated from dietary burden x transfer coefficient from Table 7.

Conclusions. Based on the dietary exposure levels and the residue data from an available ruminant feeding study, the existing pyrimethanil tolerances have been reassessed. The appropriate tolerances are:

for the combined residues of pyrimethanil and AEC614276 (4-[4,6-dimethyl-2-pyrimidinyl]amino]phenol) in:

Sheep, kidney; Goat, kidney; Horse, kidney; Cattle, kidney 2.5 ppm

and for the combined residues of pyrimethanil and AEC614277 (4,6-dimethyl-2-(phenylamino)-5-pyrimidinol) in:

Milk 0.05 ppm

The petitioner is required to submit a revised Section F.

860.1500 Crop Field Trials

Pace International LLC has submitted magnitude of the residue data for pyrimethanil following postharvest treatment of apples and pears via thermal fogging. These studies have been reviewed, and the Executive Summaries of DERs are reproduced below followed by a crop conclusion.

Postharvest Studies Conducted in Belgium

DER Reference List 47203201.der.doc (includes MRID 47271201)

Two postharvest studies were conducted in Belgium in 2001 to investigate the magnitude of the residue of pyrimethanil in/on pears and apples following postharvest application via aqueous dip, aerobrume, or electrofog treatment. The test substance used for some treatments contained multiple active ingredients (MAI) of pyrimethanil and imazalil. This document addresses residue data only for pyrimethanil.

In a study reported in MRID 47203201, unwashed and freshly harvested pear fruits were transported to a treatment facility and treated with pyrimethanil. For dip treatment, the 10% EC formulation was applied by dipping fruits onto pyrimethanil solutions of 139-322 ppm for 30 seconds. For electrofog treatment, the 10% SC formulation was applied at a rate of 0.32 oz ai/ton (~1.0x the maximum proposed rate for thermal fogging). The treated fruits were allowed to surface dry prior to sample collection, and the collected samples were stored frozen for ~30 days prior to residue analysis. Table 9 summarizes the results of postharvest field test using electrofog treatment. Maximum residues of pyrimethanil in/on treated pears were: (i) 0.60 ppm after dip treatment at 322 ppm; and (ii) 4.1 ppm after electrofog treatment at 0.32 oz ai/ton. Samples were analyzed for pyrimethanil residues using a GC/MS method which is adequate for

data collection based on concurrent method recoveries.

In a study reported in MRID 47271201, apples were treated with pyrimethanil following postharvest application via aqueous dip, aerobrume, or electrofog treatment. Dip treatment was made using the 10% EC formulation at 137-621 ppm for 30 seconds, aerobrume treatment was made using the 15% EC formulation at 0.08-0.32 oz ai/ton, and electrofog treatment was made using the 16% SC formulation at 0.17-0.38 oz ai/ton (~0.6-1.3x). Maximum residues of pyrimethanil in/on treated apples were: (i) 2.62 ppm from samples collected immediately following dip treatment at 621 ppm; (ii) 2.17 ppm from samples collected 7 months following dip treatment at 621 ppm; (iii) 7.42 ppm following aerobrume treatment at 0.14 oz ai/ton; (iv) 8.62 ppm from samples collected immediately following electrofog treatment at 0.28 oz ai/ton; and (v) 9.47 ppm from samples collected 7 months following electrofog treatment at 0.38 oz ai/ton; see Table 9. Samples were analyzed for pyrimethanil using an adequate GC/MS method. Prior to residue analysis, samples were stored frozen for maximum durations of 233 days. There are adequate storage stability data to validate sample storage conditions and intervals.

Table 9. Summary of Residue Data from Postharvest Trials with Pyrimethanil.									
Commodity	Method of Applic.	Total Applic. Rate (oz ai/ton)	Pyrimethanil Residue Levels (ppm)						
			n	Min.	Max.	HAFT ¹	Median	Mean	Std. Dev.
Pome Fruits (proposed use = 0.3 oz ai/ton total application rate)									
Pears	Postharvest electrofog	0.32	2	2.92	4.1	NA ¹	3.51	3.51	--
Apples (sampled on the same day of treatment)	Postharvest electrofog	0.17	4	1.69	6.2	NA	4.02	3.98	1.94
		0.28	4	4.28	8.62	NA	5.21	5.83	1.96
		0.38	4	4.92	7.94	NA	5.22	5.83	1.43
Apples (sampled after 7 months of treatment and storage)	Postharvest electrofog	0.17	4	1.65	6.81	NA	4.50	4.36	2.13
		0.28	4	5.46	8.68	NA	5.60	6.33	1.57
		0.38	4	5.43	9.47	NA	6.61	7.03	1.72

¹ HAFT = Highest-Average Field Trial; NA = Not applicable to this submission.

Postharvest Studies Conducted in WA State and France

DER Reference List 47201502.der.doc (includes MRID 47226701)

Two postharvest studies were conducted to investigate the magnitude of the residue of pyrimethanil in/on apples following postharvest application via electrofog treatment.

A small-scale study (MRID 47226701) was conducted in WA State in 2007 at a simulated commercial pome fruit cold-storage facility. A 16% SC formulation of pyrimethanil was applied undiluted to Red Delicious variety of apples inside storage bins using an electric thermal fogger at a rate of 0.30 oz ai/ton (1.0x). No spray adjuvants were added to the test substance. Fruits samples were randomly collected from the treated crates on the day of application, and the collected samples were stored frozen for ~67 days prior to residue analysis. There are adequate storage stability data to support sample storage conditions and durations. Samples were analyzed for pyrimethanil residues using a GC/MS method which is adequate for data collection based on concurrent method recoveries. Maximum residues of pyrimethanil in/on treated apples were 0.882 ppm.

Another postharvest study (MRID 47201502) on apples was conducted in France in 2007. The test formulation (Xedathane A, 16% SC) was applied undiluted as a thermal fog to crated mature Jonagold variety of apples inside storage bins at a rate of 0.28 oz ai/ton (~0.9x). No spray adjuvants were added to the test substance. Fruit samples were collected on the day of application, and samples were collected according to an established pattern to investigate the relation of pyrimethanil residues to sample position within the treatment cell. The collected samples were stored frozen for 5-7 days prior to residue analysis. Samples were analyzed for pyrimethanil residues using a GC/MS method which is adequate for data collection based on concurrent method recoveries. Maximum residues of pyrimethanil in/on treated apples were 2.33 ppm; see Table 10. Higher residues were observed in/on samples collected from the tops of the palloxes than those collected from the bottoms. Residues were also higher in/on samples collected from the back of the treatment cell (farther from the thermofogger) than those samples collected from the front of the cell.

Table 10. Summary of Residue Data from Postharvest Trials with Pyrimethanil.									
Commodity	Method of Applic.	Total Applic. Rate (oz ai/ton)	Pyrimethanil Residue Levels (ppm)						
			n	Min.	Max.	HAFT ¹	Median	Mean	Std. Dev.
Pome Fruits (proposed use = 0.3 oz ai/ton total application rate)									
Apple, fruit	Postharvest electrofog	0.28-0.30	20	0.25	2.33	NA ¹	1.06	1.12	0.26

¹ HAFT = Highest-Average Field Trial. NA = Not applicable to this submission.

Conclusions. Adequate postharvest data, reflecting the proposed thermal fogging of fruits according to label directions, were submitted for apples and pears, the representative crops of fruit, pome, group 11. These data indicate that following one postharvest treatment via thermal fogging of pome fruits using an SC formulation at 0.32-0.38 oz ai/ton (1.0-1.3x the proposed rate), maximum residues of pyrimethanil were 4.1 ppm in/on pears and 9.47 ppm in/on apples. The available data suggest that the proposed crop group tolerance of 14 ppm for pome fruits will not be exceeded when maximum residues from all routes of pyrimethanil exposure to pome fruits are considered (preharvest + postharvest by line spray aqueous and wax + postharvest by thermal fogging). Maximum residues following preharvest treatment at 1.59-1.62 lb ai/A (1.0x) and PHIs of 71-73 days were 0.16 ppm for apples and <0.05 ppm for pears. Maximum residues following postharvest treatment by line spray aqueous and wax at 1x were 2.84 ppm; see DP# 284866, 11/15/2004, D. Vogel *et.al*.

860.1520 Processed Food and Feed

DP#s 284001 & 284870, 01/12/2004, J. Morales and G. Kramer (PP#s 2F06439 and 2F06480)

An acceptable apple processing study (MRID 45657120) with pyrimethanil is available. The results indicate that residues of pyrimethanil reduced in apple juice (processing factor of 0.35x) but increased in wet pomace (processing factor of 4.1x). Based on the multiplication of maximum residues observed from the postharvest study (9.47 ppm) by the processing factor for wet pomace (4.1x), the maximum expected residue of pyrimethanil in apple wet pomace is 38.8 ppm. The proposed tolerance value of 56.0 ppm for apple wet pomace may be lowered to 40 ppm in order to achieve compatibility with the Codex MRL for apple dry pomace; a revised

Section F is required for this purpose. A tolerance for apple juice is not needed.

860.1650 Submittal of Analytical Reference Standards

Analytical standards for pyrimethanil, with an expiration date 09/01/2008, are currently available in the EPA National Pesticide Standards Repository (personal communication with Dallas Wright, ACB, 03/19/2007). However, standards for the regulated metabolites (AEC614276 and AEC614277) are not available. Analytical reference standards of the regulated metabolites (AEC614276 and AEC614277) should be supplied and supplies replenished as requested by the Repository. The reference standards should be sent to the Analytical Chemistry Lab, which is located at Fort Meade, to the attention of either Theresa Cole or William Chism at the following address:

USEPA

National Pesticide Standards Repository/Analytical Chemistry Branch/OPP

701 Mapes Road

Fort George G. Meade, MD 20755-5350

(Note that the mail will be returned if the extended zip code is not used.)

860.1850 and 1900 Confined and Field Accumulation in Rotational Crops

Pome fruits are typically not rotated. Therefore, residue data pertaining to confined and field accumulation in rotational crops are not germane to this tolerance petition.

860.1550 Proposed Tolerances

The Agency has determined that the residue of concern for the purpose of tolerance expression in plants is parent only. The residues of concern for tolerance expression in ruminant tissues are parent + Metabolite AEC614276, and for milk are parent + Metabolite AEC614277; see Figure 1 for chemical names and structures of these regulated compounds. The tolerance expressions proposed by the petitioner in its submission of Section F are consistent with the tolerance definitions for pyrimethanil in 40 CFR §180.518.

A summary of the recommended tolerances for the commodities addressed in the current petition is listed in Table 11.

The proposed tolerance of 14.0 ppm for pome fruits (crop group 11) is adequate and is supported by residue data reflecting the proposed use pattern. When the maximum residues from all routes of pyrimethanil exposure to pome fruits are considered (i.e., preharvest + postharvest by line spray aqueous and wax + postharvest by thermal fogging), the expected total residues ppm is below the proposed tolerance.

The proposed tolerance of 56 ppm for “pome fruit – wet pomace” should be lowered to 40 ppm to achieve compatibility with the Codex MRL for dry apple pomace.

An acceptable ruminant feeding study is available. Following adjustment of residues for storage stability corrections and calculations of transfer coefficient factors, the recommended tolerances are 2.5 ppm for the kidney of cattle, goat, horse, and sheep and 0.05 ppm for milk.

Codex maximum residue limits (MRLs; step 8/CXL) have been established for pyrimethanil *per se* in/on plant commodities. Codex MRLs have also been established for milk in terms of the sum of pyrimethanil and 2-anilino-4,6-dimethylpyrimidin-5-ol, expressed as pyrimethanil, and for livestock tissues (excluding poultry) as the sum of pyrimethanil and 2-(4-hydroxyanilino)-4,6-dimethylpyrimidine, expressed as pyrimethanil. Codex MRLs are listed for pome fruit at 7 ppm (postharvest), milk at 0.05 ppm, dry apple pomace at 40 ppm, and edible offal at 0.1 ppm. Except for apple pomace and milk, harmonization is not feasible at this time, presumably due to differences in good agricultural practices.

A Canadian MRL for pome fruit is established at 3 ppm. There are no Mexican MRLs established for residues of pyrimethanil in commodities associated with this review.

An International Residue Limit (IRL) form is appended to this Summary Document and follows this section.

Table 11. Tolerance Summary for Pyrimethanil.			
Commodity	Proposed Tolerance (ppm)	HED-Recommended Tolerance (ppm)	Comments; <i>Correct Commodity Definition</i>
40 CFR §180.518 (a)(1)			
Pome Fruits (Crop Group 11)	14.0	14	<i>Fruit, pome, group 11</i>
Pome Fruit – Wet Pomace	56.0	40	The recommended tolerance will be identical to the Codex MRL for dry pomace. <i>Apple, wet pomace</i>
40 CFR §180.518 (a)(2)			
Kidney of cattle, goat, horse, and sheep	0.6	2.5	<i>Cattle, kidney Goat, kidney, Horse, kidney, Sheep, kidney</i>
40 CFR §180.518 (a)(3)			
Milk	0.06	0.05	

References

DP#: 233092
 Subject: PP4E4384: Request for a Petition Method Validation (PMV) for Pyrimethanil in/on Imported Wine Grapes.
 From: M. I. Rodriguez
 To: D. Marlow
 Dated: 02/21/1997
 MRIDs: 43301633, 43345010, 44154401, 43301603, and 43511802

DP#: 288255
Subject: PP#2F06439. Pyrimethanil on Tree Nuts, Stone Fruit, Bulb Vegetables, Grapes, Pome Fruit, Tuber & Corm Vegetables, Strawberries, and Tomatoes. Request for Petition Method Validation (PMV) of the Proposed Analytical Enforcement for Livestock Raw Agricultural Commodities (RACs).
From: G. Kramer
To: F. Griffith
Dated: 03/10/2003
MRIDs: 45678601 & 45678602

DP#s: 284001 and 284870
Subject: PP#s 2F06439 & 2F06480. Pyrimethanil on Tree Nuts, Stone Fruit, Bulb Vegetables, Grapes, Pome Fruit, Tuber & Corm Vegetables, Strawberries, and Tomatoes. Summary of Analytical Chemistry and Residue Data.
From: J. Morales and G. Kramer
To: D. Vogel and M. Waller
Dated: 01/12/2004
MRIDs: Various

DP#: 306999
Subject: PP#2F06439. Pyrimethanil in/on Tree Nuts, Stone Fruit, Bulb Vegetables, Grapes, Pome Fruit, Tuber & Corm Vegetables, Strawberries, and Tomatoes. Results of the Petition Method Validation (PMV) of the Proposed Analytical Enforcement for Livestock Raw Agricultural Commodities (RACs).
From: S. Levy
To: S. Jenkins-Gardner and M. Waller
Dated: 09/15/2004
MRIDs: 45678601 and 45678602

DP#: 284866
Subject: PP#s: 2F6480, 9E6054, 2F6439. Pyrimethanil in/on Tree Nuts, Bulb Vegetables, Grapes, Stone Fruit (except Cherry), Pome Fruit, Citrus Fruit, Tuberous and Corm Vegetables, Strawberry, Tomato, and Imported Banana. Health Effects Division (HED) Risk Assessment. PC Code: 288201.
From: D. Vogel *et al*
To: S. Jenkins-Gardner and M. Waller
Dated: 11/15/2004
MRIDs: Various

DP#s: 332808 & 333354
Subject: PP#s 2F06439 & 2F06480. Pyrimethanil on Tree Nuts, Stone Fruit, Bulb Vegetables, Grapes, Pome Fruit, Tuber & Corm Vegetables, Strawberries, and Tomatoes. Review of Amendment Dated 8/31/06 Submitted in Response to HED's Memo of 1/12/04. Additional Storage Stability Data
From: G. Kramer
To: L. Coppolino & M. Waller
Dated: 07/16/2007
MRIDs: 46940201, 46940202, & 46926901

Attachment:
International Residue Limit Status sheet

cc: G. Kramer (RAB1)
RDI: RAB1 Chemists (4/30/08)
G.F. Kramer:S10781:PY-S:(703)305-5079:7509P:RAB1

Template Version September 2005

INTERNATIONAL RESIDUE LIMIT STATUS			
Chemical Name: 4,6-Dimethyl-N-phenyl-2-pyrimidinamine	Common Name: Pyrimethanil	X Proposed tolerance 9 Reevaluated tolerance 9 Other	Date: 03/19/2008
Codex Status (Maximum Residue Limits)		U. S. Tolerances	
X No Codex proposal step 6 or above 9 No Codex proposal step 6 or above for the crops requested		Petition Number: PP# 7F7250 DP#s: 347247 and 347248 Other Identifier:	
Residue definition (step 8/CXL): pyrimethanil for plant commodities. For compliance with MRLs for milk: the sum of pyrimethanil and 2-anilino-4,6-dimethylpyrimidin-5-ol, expressed as pyrimethanil, and for livestock tissues (excluding poultry) is the sum of pyrimethanil and 2-(4-hydroxyanilino)-4,6-dimethylpyrimidine, expressed as pyrimethanil. Note: The MRLs below are at Step 3 , but will most likely advance to CXL status this year. The 7 is from post harvest, but not therma fog, as there was no valid label at the time of the review (09/2007).		Reviewer/Branch: RAB1/G. Kramer Residue definition: Plants - Parent only Ruminant – Parent + AEC614276 Milk – Parent + AEC614277	
Crop (s)	MRL (mg/kg)	Crop(s)	Tolerance (ppm)
Pome fruit	7 post harvest	Pome Fruits (Crop Group 11)	14
Milks	0.05 (*)	Pome Fruit – Wet Pomace	56
Apple pomace, dry	40	Kidney of cattle, goat, horse, and sheep	0.60
Edible offal	0.1	Milk	0.06
Limits for Canada		Limits for Mexico	
9No Limits 9 No Limits for the crops requested		X No Limits 9 No Limits for the crops requested	
Residue definition: pyrimethanil		Residue definition: N/A	
Crop(s)	MRL (mg/kg)	Crop(s)	MRL (mg/kg)
Pome fruit	3		
Notes/Special Instructions: S.Funk, 03/23/2008.			